NOV 1 3 2000

K002680

510(k) Summary of Safety and Effectiveness

This summary of 510(k)-safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Application Information:

Date Prepared:	August 25, 2000
Submitter:	TissueLink Medical Inc.
Address:	One Washington Center Suite 400 Dover, NH 03820
Contact Person:	Roberta L. Thompson Vice President, Clinical, Regulatory and Quality
Telephone Number:	(603) 742-1515 ext. 106
Fax Number:	(603) 742-1488

Device Information:

Trade Name:	TissueLink Monopolar Floating Ball
Common Name:	Electrosurgery Cauterizing Pen
Classification Name:	Electrosurgical cutting and coagulation device and accessories, 21CFR 878.4400

Predicate Devices:

Claim of Substantial Equivalence of the TissueLink Monopolar Floating Ball is made to:

- ValleyLab E2515 ES Pencil (K791639) with ValleyLab coated blade model E1450X (K962044)

Device Description:

The TissueLink Monopolar Floating Ball is a sterile, single use device, which employs radiofrequency energy and saline irrigation to coagulate tissue. The device is equipped with a Floating Ball electrode tip. There is an on/off RF actuation switch on the hand piece and saline and electrical lines exit the end of the hand piece.

Intended Use:

The TissueLink Monopolar Floating Ball is a sterile, single use electrosurgery device intended to be used in conjunction with an electrosurgical generator for delivery of radiofrequency current and saline for hemostasis and coagulation of soft tissue at the operative site. It is intended for, but not limited to abdominal and thoracic surgery, laparoscopic procedures, endoscopic procedures and thoracoscopic procedures. The proposed device is not intended for contraceptive tubal coagulation (permanent female sterilization).

Technological Characteristics:

This device has technological characteristics identical to the predicate device.

Nonclinical Performance:

The performance characteristics of the TissueLink Floating Ball were tested and compared with performance specifications established by TissueLink Medical, Inc. for the device and with a commercially available predicate device.

Clinical Performance:

Clinical testing was not performed on this device.

Conclusions from Nonclinical Tests:

The performance of this device is substantially equivalent to the predicate device and performs as intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 13 2000

Ms. Roberta L.Thompson
Vice President, Clinical, Regulatory Affairs, and Quality
TissueLink Medical Inc.
One Washington Center Suite 400
Dover, New Hampshire 03820

Re: K002680
Trade Name: TissueLink Monopolar Floating Ball
Regulatory Class: II
Product Code: GEI
Dated: August 25, 2000
Received: August 28, 2000

Dear Ms.Thompson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for use Statement

510(k) Number (if known): K002680

Device Name: TissueLink Monopolar Floating Ball

Indications for Use:

The TissueLink Monopolar Floating Ball is a sterile, single use electrosurgery device intended to be used in conjunction with an electrosurgical generator for delivery of radiofrequency current and saline for hemostasis and coagulation of soft tissue at the operative site. It is intended for, but not limited to abdominal and thoracic surgery, laparoscopic procedures, endoscopic procedures and thoracoscopic procedures. The proposed device is not intended for contraceptive tubal coagulation (permanent female sterilization).

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109) Optional Format 1-

for Mark N Milburn

(Division Sign-Off)
Division of General Restorative Devices

510(k) Number K002680